OPTISULIN® and OPTISULIN® SoloSTAR

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Optisulin or Optisulin SoloSTAR?

Optisulin contains the active ingredient insulin glargine. Optisulin is used to reduce high blood sugar (glucose) levels in people with diabetes mellitus.

For more information, see Section 1. Why am I using Optisulin or Optisulin SoloSTAR? in the full CMI.

2. What should I know before I use Optisulin or Optisulin SoloSTAR?

Do not use if you have ever had an allergic reaction to Optisulin or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Optisulin or Optisulin SoloSTAR? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Optisulin and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Optisulin or Optisulin SoloSTAR?

Your doctor will tell you how much Optisulin you need to use each day. Your doctor may increase or decrease the dose, depending on your blood sugar levels.

More instructions can be found in Section 4. How do I use Optisulin or Optisulin SoloSTAR? in the full CMI.

5. What should I know while using Optisulin or Optisulin SoloSTAR?

Things you should do	• Remind any doctor, dentist or pharmacist

	you visit that you are using Optisulin. • Measure your blood sugar level regularly. • Keep using Optisulin even if you feel well. • Tell your doctor if you often have hypoglycaemia or if you have ever become unconscious after using Optisulin. • Always carry some sugary food or drink with you. • Tell your doctor or anybody else treating you if you are travelling.
Drinking alcohol	• Tell your doctor if you drink alcohol. • Alcohol may mask the symptoms of hypoglycemia.
Looking after your medicine	• Keep unopened cartridges and pens of Optisulin in a refrigerator where the temperature is between 2-8°C. Do not allow it to freeze. Discard if frozen.

For more information, see Section 5. What should I know while using Optisulin or Optisulin SoloSTAR? in the full CMI.

6. Are there any side effects?

Serious side effects may include low blood sugar (hypoglycaemia or 'hypo') or an allergic reaction. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

OPTISULIN® and OPTISULIN® SoloSTAR

Active ingredient: *insulin glargine (in-sue-lin glar-jeen)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Optisulin. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Optisulin.**

Where to find information in this leaflet:

1. Why am I using Optisulin or Optisulin SoloSTAR?
2. What should I know before I use Optisulin or Optisulin SoloSTAR?
3. What if I am taking other medicines?
4. How do I use Optisulin or Optisulin SoloSTAR?
5. What should I know while using Optisulin or Optisulin SoloSTAR?
6. Are there any side effects?
7. Product details

1. Why am I using Optisulin or Optisulin SoloSTAR?

Optisulin contains the active ingredient insulin glargine. Optisulin is an antidiabetic agent used to reduce high blood sugar.

Optisulin is used to reduce high blood sugar (glucose) levels in people with diabetes mellitus.

Optisulin is a modified insulin that is very similar to human insulin. It is a substitute for the insulin produced by the pancreas.

Optisulin is a long-acting insulin. Your doctor may tell you to use a rapid-acting human insulin or oral diabetes medication in combination with Optisulin.

Optisulin is not addictive.

Ask your doctor if you have any questions about why Optisulin has been prescribed for you.

2. What should I know before I use Optisulin or Optisulin SoloSTAR?

Warnings

Do not use Optisulin if:

- you are allergic to insulin glargine, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

- any medicine containing insulin

Some of the symptoms of an allergic reaction may include:

- redness, swelling, rash and itching at the injection site
- rash, itching or hives on the skin
- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body

If you are experiencing low blood sugar levels (hypoglycaemia - a "hypo").

If you have a lot of hypos discuss appropriate treatment with your doctor.

After the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you use Optisulin after the expiry date has passed, it may not work as well. If it has expired or is damaged, return it to your pharmacist for disposal.

If the product appears cloudy, discoloured or contains particles, or if the injection pen/cartridge appears damaged.

If you are not sure whether you should start using this medicine, talk to your doctor.

Do not give Optisulin to children less than 6 years of age.

There is no experience with the use of Optisulin in children less than 6 years.

Check with your doctor if you:

- have any other medical conditions such as kidney problems or liver problems
- take any medicines for any other conditions

Tell your doctor if:

- you drink alcohol
- you do not eat regular meals
- you do a lot of exercise
- you are ill or feeling unwell

Alcohol, diet, exercise and your general health all affect the control of your diabetes.

If you have not told your doctor about any of the above, tell them before you start using Optisulin.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Pregnancy may make managing your diabetes more difficult.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Medicines that may increase the blood sugar lowering effect of Optisulin include:

- oral antidiabetic medicines that are used to treat type 2 diabetes
- blood pressure, blood flow, cholesterol and heart medications
- medications for pain and inflammation
- some antidepressants
- sulfonamide antibiotics

Medicines that may reduce the blood sugar lowering effect of Optisulin include:

- corticosteroids, glucagon and other hormonal therapies
- estrogens, progestogens, oral contraceptives and gynaecological medications
- fluid and glaucoma medications
- tuberculosis and HIV/AIDS treatments
- some psychiatric medications
- adrenaline (epinephrine) and asthma medications such as salbutamol, terbutaline

Certain heart medications, especially beta-blockers, may mask the symptoms of hypoglycaemia.

- Your doctor and pharmacist have a full list of medicines with which you must be careful or avoid while using Optisulin. Please check with your doctor or pharmacist before starting any new medicines or over the counter products.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Optisulin.

4. How do I use Optisulin or Optisulin SoloSTAR?

How much to use

- Your doctor will tell you how much Optisulin you need to use each day. Your doctor may increase or decrease the dose, depending on your blood sugar levels.
- It is very important that you manage your diabetes carefully. Too much or too little insulin can cause serious effects.

When to use Optisulin

- Your doctor will tell you when to use Optisulin.
- Optisulin should be used once a day, at the same time every day.

How to use Optisulin

Optisulin is a clear solution that does not require shaking before use.

Your doctor, pharmacist or diabetes educator will have shown you how to use Optisulin.

Inject Optisulin into your thighs, upper arms or the front of your waist (abdomen).

Change the place within the area you inject each day. This will reduce the risk of skin shrinking or thickening or lumps at the site (see "Side effects").

Do not use the exact same spot for each injection.

Do not inject where the skin has pits, is thickened, or has lumps.

Do not inject where the skin is tender, bruised, scaly or hard, or into scars or damaged skin.

Carefully follow all the directions.

Do not dilute Optisulin.

Do not mix Optisulin with any other insulin or solution.

Do not inject Optisulin into a vein.

Optisulin is intended for injection under the skin. It can be injected at any time during the day, however, at the same time every day.

Any change in this medicine should be made cautiously and only under medical supervision.

If you do not understand the instructions, ask your doctor, pharmacist, or diabetes educator for help.

ALWAYS CHECK YOUR OPTISULIN INJECTION PEN OR CARTRIDGE.

Do not use Optisulin if it is no longer clear and colourless or if it contains particles.

Make sure you are using the correct injection pen or cartridge.

Always check the insulin label on the cartridge or reusable pen before each injection to make sure you are using the right insulin.

Keep the cartridge or injection pen at room temperature for 1 or 2 hours before use. Cold insulin is more painful to inject.

If you develop skin changes at the injection site. The injection site should be rotated to prevent skin changes such as lumps under the skin. The insulin may not work very well if you inject into a lumpy area. Contact your doctor if you are currently injecting into a lumpy area before you start injecting in a different area. Your doctor may tell you to check your blood sugar more closely, and to adjust your insulin or your other antidiabetic medications dose.

For Optisulin cartridges or injection pens

PREPARING A DOSE FOR INJECTION

Always do a safety test before use.

The safety test may highlight a problem with your injection pen. The safety test also removes any air bubbles and helps indicate whether or not a needle is bent or broken.

Becton Dickinson (BD Micro-Fine™+) needles should be used with injection pens.

Reusable pens

Optisulin cartridges should only be used with the AllStar, AllStar Pro, JuniorStar or ClikStar reusable pens.

Carefully follow the instructions provided with the pen, for loading a cartridge, attaching a needle, performing a safety test and administering the insulin injection.

If the reusable injection pen does not work properly, Optisulin may be withdrawn from the cartridge into a syringe. Ask your doctor, pharmacist or diabetes educator for help.

Pre-filled disposable pens

Optisulin SoloStar disposable pens are pre-filled and ready to use. Once all the insulin is used you cannot replace the cartridge.

Carefully follow the instructions provided with the Optisulin SoloStar pen for attaching a needle, performing a safety test and administering the insulin injection.

Never use an injection pen if it is damaged or you are not sure that it is working properly. Use a new pen.

INJECTING A DOSE

Optisulin should be injected under the skin, being careful not to inject it into a muscle or vein.

Choose a site for injection.

Inject Optisulin into the abdomen, thighs or upper arms.

1. With one hand, stabilise the skin by spreading it or pinching up a large area, as recommended by your healthcare professional.
2. Insert the needle into the skin as recommended by your healthcare professional.
3. Inject the full dose of Optisulin by pushing the plunger as far as it will go.
4. Slowly count to 10 before removing the needle from the skin.

Use a different injection site each injection so that the same site is not used more often than once a month.

- This will reduce the chance of local skin reactions developing.

AFTER INJECTING

Using the outer needle cap, unscrew the needle and dispose of it safely into a sharps container.

Do not share needles, cartridges or injection devices. Do not reuse needles.

Leave the cartridge in the reusable pen until it needs to be replaced.

Do not attempt to replace the cartridge in a pre-filled disposable pen.

- Empty disposable pens must never be reused and must be properly discarded.

If you forget to use Optisulin - Hyperglycemia

Optisulin should be used regularly at the same time each day. If you forget to take your insulin dose, test your blood sugar level as soon as possible.

Optisulin is a long-acting insulin that works for 24 hours and should be taken regularly at the same time each day. If you miss taking your dose at the regular scheduled time, your blood sugar levels may become high (hyperglycaemia).

However, taking a dose of Optisulin at another time may increase your risk of having a hypo. You should therefore plan in advance with your doctor or healthcare professional so that you know what to do in case you miss a dose.

If you have missed a dose and are not sure what you should do, contact your doctor or healthcare professional for specific advice.

Do NOT use a double dose of your insulin.

If you double a dose, this may cause low blood sugar levels.

The risk of hyperglycaemia is increased if you:

- miss doses of Optisulin or other insulin, or use less Optisulin than you need
- have uncontrolled diabetes
- exercise less than usual

- eat more carbohydrates than usual
- are ill or stressed
- take certain other medications

High blood sugar levels over a period of time can lead to too much acid in the blood (diabetic ketoacidosis).

Contact your doctor immediately if your blood sugar level is very high or you experience any of the following symptoms.

Symptoms of mild to moderate hyperglycaemia include:

- drowsy feeling
- flushed face
- thirst, loss of appetite
- fruity odour on the breath
- blurred vision
- passing larger amounts of urine than usual
- getting up at night more often than usual to pass urine
- high levels of glucose and acetone in the urine

Symptoms of severe hyperglycaemia include:

- heavy breathing
- fast pulse
- nausea, vomiting
- dehydration
- loss of consciousness
- Severe hyperglycaemia can lead to unconsciousness and, in extreme cases, death if untreated.

Discuss any worries you may have about this with your doctor, pharmacist or diabetes educator.

If you use too much Optisulin - Hypoglycemia, a "Hypo"

If you accidentally use too much Optisulin your blood sugar level may become too low (hypoglycaemia) and you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**)
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

The risk of hypoglycaemia is increased if you:

- accidentally use too much Optisulin
- have too much or unexpected exercise
- delay eating meals or snacks
- eat too little food
- are ill

The first symptoms of mild to moderate hypoglycaemia can come on suddenly. They may include:

- cold sweat, cool pale skin
- fatigue, drowsiness, unusual tiredness and weakness
- nervousness, anxious feeling, tremor, rapid heartbeat
- confusion, difficulty concentrating
- excessive hunger

- vision changes
- headache, nausea

Always carry some sugary food or drink with you.

If you experience any of these symptoms of hypoglycaemia, you need to raise your blood sugar urgently. You can do this by taking one of the following:

- 5-7 jelly beans
- 3 teaspoons of sugar or honey
- 1/2 can of a sugar-containing soft drink (not a diet soft drink)
- 2-3 concentrated glucose tablets

Follow up with extra carbohydrates, e.g. plain biscuits, fruit or milk, when over the initial symptoms.

Taking this extra carbohydrate will prevent a second drop in your blood sugar level.

If not treated quickly, the initial symptoms of hypoglycaemia may progress to loss of co-ordination, slurred speech, confusion, loss of consciousness and seizures.

If severe hypoglycaemia is not treated, it can cause brain damage and death.

Tell your relatives, friends, close workmates or carers that you have diabetes.

It is important that they recognise the signs and symptoms of a "hypo".

Make sure they know to turn you on your side and get medical help immediately if you lose consciousness.

Make sure they know not to give you anything to eat or drink if you are unconscious.

This is because you could choke.

Provide them with the telephone number for your doctor, the Poisons Information Centre (13 11 26) and Emergency Services.

An injection of the hormone glucagon may speed up recovery from unconsciousness. This can be given by a relative, friend, workmate or carer who knows how to give it.

If glucagon is used, have some sugary food or drink as soon as you are conscious again.

If you do not feel better after this, contact your doctor, diabetes educator, or the closest hospital.

If you do not respond to glucagon treatment, you will have to be treated in a hospital.

See your doctor if you keep having "hypos" or if you have ever become unconscious after using Optisulin.

Your dose of Optisulin or other medicines may need to be changed

5. What should I know while using Optisulin or Optisulin SoloSTAR?

Things you must do

Measure your blood sugar level regularly.

This is the best way to tell if your diabetes is being controlled properly. Your doctor or diabetes educator will show you how and when to do this.

It is important to keep using Optisulin even if you feel well.

Optisulin helps to control your condition, but does not cure it.

Tell your doctor if you often have hypoglycaemia or if you have ever become unconscious after using Optisulin.

Your doctor may need to adjust your dose of Optisulin or of other medicines you are taking.

Always carry some sugary food or drink with you.

If you experience any of the symptoms of hypoglycaemia, immediately eat some sugary food or have a drink, e.g. jelly beans, sugar, honey, sugar-containing soft drink, glucose tablets. Diet and low calorie soft drinks do NOT contain sugar and are unsuitable to take for hypoglycaemia.

Make sure that you tell every doctor, dentist, pharmacist or other healthcare professional who is treating you that you have diabetes and are using Optisulin.

Tell your doctor, pharmacist or diabetes educator if you are travelling.

Ask your doctor for a letter explaining why you are taking injecting pens and needles with you. Each country you visit will need to see this letter, so you should take several copies.

You may need to inject Optisulin and eat your meals at different times because of time differences in and between countries.

If you are travelling, it is a good idea to:

- wear some form of identification showing you have diabetes
- carry some form of sugar to treat hypoglycaemia if it occurs, e.g. sugar sachets or jelly beans
- carry emergency food rations in case of a delay, e.g. dried fruit, biscuits or muesli bars
- keep Optisulin readily available; take enough Optisulin for your expected needs whilst travelling - you may not be able to get Optisulin in the country you are visiting

Your doctor, pharmacist or diabetes educator can provide you with some helpful information.

Tell your doctor if you are having trouble or difficulty with your eyesight.

Visit your doctor for regular checks of your eyes, feet, kidneys, heart, circulation, blood and blood pressure.

Carefully follow your doctor's and/or dietician's advice on diet, drinking alcohol and exercise.

Things you must not do

Do not stop using Optisulin unless your doctor tells you to.

Do not skip meals while using Optisulin.

Do not use Optisulin if you think it has been frozen or exposed to excessive heat (temperatures above 30°C).

Do not reuse empty cartridges.

Do not give Optisulin to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Optisulin affects you. Be careful not to let your blood sugar levels fall too low.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may mask the symptoms of hypoglycemia.

Things to be careful of

Tell your doctor if you are ill.

Illness, especially with nausea and vomiting, may cause your insulin needs to change. Even if you are not eating, you still require insulin. You and your doctor should design an insulin plan for those times when you are sick.

If you become sick with a cold or flu, it is very important to continue using Optisulin, even if you feel unable to eat your normal meal. If you have trouble eating solid foods, use sugar-sweetened drinks as a carbohydrate substitute or eat small amounts of bland food.

Your diabetes educator or dietician can give you a list of foods to use for sick days.

Tell your doctor if you are exercising more than usual.

Exercise may lower your need for Optisulin. Exercise may also speed up the effect of a dose of Optisulin, especially if the exercise involves the area of the injection site (e.g. the thighs should not be used for injection prior to jogging or running).

Tell your doctor if your diet changes.

Changes in diet may cause your insulin needs to change.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Storage

CARTRIDGES

Keep unopened cartridges of Optisulin in a refrigerator where the temperature is between 2-8°C. Do not allow it to freeze. Discard if frozen.

When the cartridge has been inserted into the injection pen, the cartridge-pen combination should not be put in the refrigerator and should be kept below 30°C. Do not leave it near heat or in direct light. Discard the cartridge within 28 days of first use. Cartridges that are first carried as a spare for a while must also be discarded 28 days after being removed from the refrigerator.

PRE-FILLED DISPOSABLE PENS

Before use, keep unopened Optisulin pre-filled pens in a refrigerator where the temperature is between 2-8°C. Do not allow it to freeze. Discard if frozen.

Before first use, store the pre-filled pen at room temperature for 1 to 2 hours. Once in use, the pre-filled pen should not be put in the refrigerator and it should be kept below 30°C. Do not leave it near heat or in direct light. Discard the pre-filled pen within 28 days of first use. Pre-filled pens that are first carried as a spare for a while must also be discarded 28 days after being removed from the refrigerator.

When to discard your medicine (as relevant)

Dispose of your insulin syringes, needles and disposable injection devices safely into a sharps container.

If your doctor tells you to stop using Optisulin or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Optisulin helps most people with diabetes, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor, pharmacist or diabetes educator to answer any questions you may have.

The most common side effect when using insulin is low blood sugar levels (hypoglycaemia - a "hypo").

Less serious side effects	What to do
General: • hypoglycaemia (mild to moderate) **Skin related:** • redness, swelling or itching at the injection site; usually these symptoms disappear within a few weeks during continued use • a depression or thickening of the skin around the injection site (lipodystrophy); this can often occur if you inject too often at the same injection site	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Skin changes at the injection site:
If you inject insulin too often at the same place, the fatty tissue may either shrink (lipoatrophy) or thicken (lipohypertrophy). Lumps under the skin may also be caused by build-up of a protein called amyloid (localized cutaneous amyloidosis). The insulin may not work very well if you inject into a lumpy area. Change the injection site with each injection to help prevent these skin changes.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

Serious side effects	**What to do**
More severe symptoms of hypoglycaemia, including: • disorientation • seizures, fits or convulsions • loss of consciousness **Signs of a serious allergic reaction, including:** • skin rashes over a large part of the body • shortness of breath, wheezing • swelling of the face, lips or tongue • fast pulse • sweating	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

The above list includes some very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems.

By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Optisulin contains

Active ingredient **(main ingredient)**	Insulin glargine (100 Units/ mL)
Other ingredients **(inactive ingredients)**	metacresol glycerol zinc chloride hydrochloric acid

	sodium hydroxide water for injections
Potential allergens	N/A

Do not take this medicine if you are allergic to any of these ingredients.

What Optisulin and Optisulin SoloSTAR look like

Optisulin is a clear, colourless solution available in 3mL cartridges. AUST R 159295

Optisulin SoloSTAR is a pre-filled disposable pen containing a 3mL cartridge of Optisulin. AUST R 159302

Who distributes Optisulin and Optisulin SoloSTAR

Distributed by:

sanofi-aventis australia pty ltd

International Tower 3, Level 23

300 Barangaroo Avenue

Sydney NSW 2000

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

® = Registered Trademark

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Full Product Information is available from sanofi-aventis australia pty ltd by calling 1800 818 806

Further information

You can get more information about diabetes and insulin from Diabetes Australia:

Freecall helpline 1800 177 055

www.diabetesaustralia.com.au

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